IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Aleta Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE THE TESTIMONY OF DR. CHARLES KING

Plaintiff, by and through her attorneys, respectfully requests that this Court deny in its entirety Defendants' motion *in limine* to exclude the testimony of Dr. Charles King III.

I. PRELIMINARY STATEMENT

Defendants' motion to exclude the testimony of Dr. Charles King should be denied for the following reasons:

1. Dr. King is a very qualified marketing economist who has used sound economic and marketing principles to assess the role that Defendants' illegal off-label marketing and promotion program in the off-label sales and prescriptions of Neurontin for illnesses for which it was not approved by the FDA and for which there was little or no evident scientific support.

2. Dr. King's opinions have a nexus to the case and fit the case. Dr. King has reviewed and analyzed Defendants' marketing and promotion plans and identified a number of

illegal and improper ways that Defendants persuaded doctors to prescribe Neurontin off-label. Furthermore, Dr. King opines that the company was aware of the extensive off-label use of Neurontin at a time when the company was suppressing negative information that was important to patients and doctors for those very off-label uses. Mr. Smith died after taking Neurontin for unapproved medical purposes after Defendants' employees repeatedly urged Mr. Smith's health care providers to prescribe Neurontin for off-label purposes in the ways that Dr. King has identified as improper but effective marketing practices. Mr. Smith's doctors have testified that if they had known of the information suppressed by defendants, they would have acted differently with respect to Mr. Smith. *See* Point B *infra.*

3. Dr. King did form and express opinions about the extent to which Defendants' illegal marketing campaign led to improper off-label prescriptions. Defendants' assertions in that regard are groundless.

4. Dr. King was not improperly influenced by Plaintiff's counsel. Judge Patti B. Saris, the Neurontin MDL presiding Judge, has already dismissed one of many defense complaints and found that Keith L. Altman[1] was doing ministerial-only tasks under the direction of the expert, which was the equivalent of doing secretarial work.

5. Judge Saris has already denied the defense motion to exclude evidence of Defendants' marketing and illegal promotion of Neurontin; this Court should not reach a different or inconsistent result with Judge Saris' order.

6. Judge Saris and Judge William G. Young, who undertook trial of *Shearer v Pfizer Inc.* on March 30, 2010, at Judge Saris' request, have already denied two motions to exclude Dr. King's testimony under Fed. R. Evid. 702. This Court should not reach a different or inconsistent result with those orders.

[1] Mr. Altman was an employee/law student for Finkelstein & Partners LLP at the time; he has since passed the bar.

7. Defendants' motion is untimely. Defendants neglected to file a *Daubert-Kumho-Joiner* motion to disqualify in the time specified by Discovery Order 7 for MDL-generic experts. MDL Docket No. 582.

II. AUTHORITY – GENERAL PRINCIPLES

The Supreme Court in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153 (1999), made clear that the in ruling on admissibility of expert testimony, the Court has broad discretion and latitude. Specifically, the *Kumho* Court wrote that the "test of reliability is 'flexible' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts in every case." The Court went on to say that "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id.* at 141-42.

While the Supreme Court rejected any litmus test for admissibility, it did note that the touchstone for admissibility was "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the **same level of intellectual rigor** that characterizes the practice of an expert in the relevant field." *Id.* at 152 (emphasis added). This sentiment was echoed in the Advisory Committee's notes to the December 2000 amendment to Rule 702 and its companion rules. As that commentary points out, the Court rejected the suggestion of codifying the *Daubert* factors and opted, instead, to add the following language to Rule 702 as:

> … if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods to the facts of the case.

Pharmaceutical marketing practices are not an exact science. Indeed, they are secretive and hidden from public view. Thus, in applying the standards set forth in *Daubert, Kumho Tire*

and *Joiner* to the case at bar regarding an expert opinion on marketing practices of a pharmaceutical company, the test is "flexible" and must "fit the facts of the case." Dr. King's testimony is in a scholarly discipline that is not premised upon hard science. *See Securities & Exch. Comm'n v. Johnson,* 525 F. Supp. 2d 66 (D.D.C. 2007). Consequently, this Court should exercise such flexibility when evaluating a marketing expert opinion.

Testimony which is simply not amenable to the scientific method should not be subjected to the strictures of *Daubert* and instead passes as "specialized knowledge":

> Because there are areas of expertise, such as "social science in which the research, theories and opinions cannot have the exactness of hard sciences methodologies, trial judges are given broad discretion whether the *Daubert* specific factors are, or are not, reasonable measures of reliability in a particular case.[2]

United States v. Simmons, 470 F.3d 1115, 1123 (5th Cir. 2006).

Dr. King has specialized knowledge and he formulated his opinions with the same considerable "intellectual rigor" he applies in his own professional life based on the best available facts or data. His opinions are reliable, and Defendants' motion should be denied.

A. **Dr. King's Qualifications and Methods**

Dr. King has an A.B. from Harvard, a J.D. from Yale, and a Ph.D. in economics from MIT. He taught marketing and economics at Harvard until 2003, including courses on information and marketing networks, economics and statistics, marketing, competition and strategy. He has performed research in and published in the field of pharmaceutical marketing, including studies on NSAIDs, Tricor, Zantac, Vioxx, Paxil, Relafen, and other health care

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[2] *See also United States v. Hall*, 974 F. Supp. 1198, 1200 (C.D. Ill. 1997) (*citing* Jennifer Laser, *Inconsistent Gatekeeping in Federal Courts: Application of Daubert v. Merrell Dow Pharmaceuticals, Inc. to Nonscientific Expert Testimony*, 30 Loy. L.A. L. Rev. 1379 (1997); Teresa S. Renaker, *Evidentiary Legerdemain: Deciding When Daubert Should Apply to Social Science Evidence*, 84 Cal. L. Rev. 1657 (1996); Edward J. Imwinkelried, *The Next Step After Daubert: Developing a Similarly Epistemological Approach to Ensuring the Reliability of Nonscientific Expert Testimony*, 15 Cardozo L. Rev. 2271 (1994)).

products. Dr. King's report, including his CV, qualifications, experience[3] and his Declaration, are referenced as if fully incorporated herein.

Dr. King undertook to determine whether Warner-Lambert and Pfizer improperly marketed Neurontin, how they did so, and what the consequences are. In general, it is illegal for a pharmaceutical company to promote drugs for the treatment of any illness for which the FDA has not granted approval. That is called off-label marketing.

From confidential internal company documents as well as government records, scholarly studies, and sales and industry data, Dr. King studied the operating, business, marketing, and promotional plans of those companies from 1994 to 2004. To quote from his Declaration:

> 4. My assignment was to review case materials, company documents, sales and marketing data and reports, published academic studies and other materials and to compile, synthesize and analyze these materials as they apply to the marketing of Neurontin. The outcome of my review culminated in my written expert report and opinions. In forming my opinions, I applied standard methods and my expertise and experience in marketing and economics. I systematically looked for materials, both case materials and academic research, relevant to the issues in the case. In addition, when appropriate, I considered other alternative explanations for my conclusions to determine their validity. These methods are similar to those commonly used in refereed academic publications undertaking similar analysis. For example:
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> - See the Steinman article, "Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents," which appeared in the scientific journal, *Annals of Internal Medicine*, which undertook identical methods in reaching their conclusion that "[a]ctivities traditionally considered independent of promotional intent, including continuing medical education and research, were extensively used to promote gabapentin. New strategies are needed to ensure a clear separation between scientific and commercial activity."
> - See Scherer, "The Pharmaceutical Industry" which was published in the Handbook of Health Economics. The methods used in this review article are to analyze, compile and synthesize published academic research and to form opinions about health care economics.
> - See the Fung article, "Systematic Review: The Evidence that Publishing Patient Care Performance Data Improves Quality of Care." The purpose

[3] Declaration of Kenneth B. Fromson, Ex. A King Report and CV.

> of this research was "to synthesize the evidence for using publicly reported performance data to improve quality." Based on this, the authors conclude that "[e]vidence suggests that publicly releasing performance data stimulates quality improvement activity at the hospital level."
>
> - See Rosenthal and Frank, "What is the Empirical Basis for Paying for Quality in Health Care?" where "The authors review the empirical literature on paying for quality in health care and comparable interventions in other sectors. They find little evidence to support the effectiveness of paying for quality."
>
> 5. In summary, these are just a few examples of methods commonly used and accepted in academic research and in health care economics. I use these same standard methods in my report to reach my conclusions.

Declaration of Dr. Charles King at ¶¶ 4-5, attached as Exhibit B to Fromson Declaration.

All these methods and approaches are standard, well-established techniques in the scientific, economic and marketing research literature. *See Spokane Tent & Awning, Inc. v. Sonoco Prods. Co.,* No. CS-00-371-RHW, 2001 U.S. Dist. LEXIS 26236 (E.D. Wash. Sept. 13, 2001) (court found marketing expert opinion admissible where he relied on primary marketing principles that had been published in textbooks and journals and "tested by the marketing community"); *Heien v. Colson Caster Corp.,* No. 03-CV-182-J, 2004 U.S. Dist. LEXIS 30741 (D. Wyo. Jun. 29, 2004) (court found marketing expert methodology admissible where expert employed utilized eight step program had been peer reviewed in textbooks published and where he had derived his opinions based on documents and witness testimony); *Securities & Exch. Comm'n v. Johnson,* 525 F. Supp. 2d 66 (marketing expert testimony found admissible where "his report and conclusions therein are drawn from many years of experience in Internet marketing and eCommerce, and are derived from significant research."). Dr. King's methodology included the review and analysis of the existing literature.[5] Defendants' themselves

[5] Fromson Decl., Ex. A, King Report at ¶ 15 and Attachment B.

review sales and marketing data to determine the effectiveness of their marketing efforts[6]. Dr. King used standard methods substantially like the Defendants' methods in reviewing the sales and marketing data produced by Defendants to Plaintiffs. Dr. King also reviewed company documents and placed them into context. Much has been done by others who have published on the marketing of Neurontin in the peer reviewed literature[7].

Dr. King reviewed in excess of one million pages of Warner-Lambert/Pfizer records, including depositions of their marketing employees and emails of marketing and promotional employees. He adopted and applied the analyses of pharmaceutical marketing scholarly studies: (1) of the effect of marketing practices on doctors; (2) of the percentages of total prescriptions of drugs that can be anticipated for off-label prescribing; (3) of the effects of negative information about a drug on the prescribing practices of doctors; and (4) of incentives for illegal promotion of drugs, and many related matters. The scholarly studies are listed in part in Attachment B to Dr. King's Report.[8] He analyzed sales and numbers of prescriptions, sales contacts, numbers of samples, and numbers of publications, including those that would be expected from legal promotion for epilepsy and, after 2002, post-herpetic neuralgia.[9]

From these records and documents, Dr. King determined that not only did Warner-Lambert pursue a plan to aggressively market Neurontin off-label, for which it pleaded guilty to criminal charges, but it also continued to pursue this plan through and beyond 2000, when Pfizer took over.[10]

The plan included, *inter alia*, having sales representatives go to the offices of doctors who would not be expected to treat the approved indication, epilepsy, and promote Neurontin to

[6] Fromson Decl., Ex. C. This is a chart prepared by Pfizer employee Nancy Mancini analyzing various sales data.
[7] Fromson Decl., Ex. D.
[8] Fromson Decl., Ex. A, King Report.
[9] *Id*. at ¶ 15 and Attachment B.
[10] Fromson Decl., Ex. A *See, inter alia,* King Report, ¶¶ 16–66.

these doctors for prescribing for neuropathic pain, for bipolar and psychiatric disorders, and many other conditions. The plan included publication of scientifically-thin reports of Neurontin and to pay doctors to sign their names as authors, to pay for trips, meals, tickets, and to conduct conferences at which Neurontin was improperly promoted, to misrepresent that Neurontin was safe for conditions for which it had not been approved and tested, and to suppress negative information about Neurontin from the doctors by delaying publication of negative reports.[11] At no point during his deposition did Defendants ask Dr. King about his methods, with the exception of asking once in his deposition if he used a term search feature to seek out the places in a computer file where the term appeared.

Dr. King analyzed the sales and promotion plans, the incentives and records, and formed opinions that the illegal off-label promotion scheme continued from 1995 through the period Pfizer took over Warner-Lambert and beyond, and that the off-label promotion scheme produced over 70% of all Neurontin prescriptions by the end of that period and generated some $10,000,000,000 (billion) in sales for a drug that was estimated in 1995 to generate $500,000,000 (million) during its product life.[12]

Dr. King specifically concluded that:

- The marketing and promotional efforts of Warner-Lambert and Pfizer were significant contributing factors to the off-label sales of Neurontin.
- Off-label sales of Neurontin would have continued had Pfizer ceased off-label promotional activities for Neurontin.
- The suppression of information about serious adverse events enabled growth in off-label sales.
- Pfizer's off-label marketing of Neurontin indirectly influenced all, or

[11] *Id.*, and data in footnotes 30 to 158 in which the company documents, deposition testimony, sales records, and emails are quoted or referenced by Dr. King.

[12] Fromson Decl., Ex. A, King Report at¶ 16.

substantially, all physicians prescribing of Neurontin.[13]

Dr. King may interpret documents he reviewed in arriving at his opinions. Defendants' documents are not self-explanatory and certainly not to a lay person. There is no uniform model or format for such marketing documents, such as operating plans, operating goals, marketing plans, publication plans, sales tracking statistics, or prescription tracking statistics. In the case of Warner-Lambert/Pfizer documents provided to Dr. King, such documents included world-wide, United States national, and regional customer business unit documents, memoranda, emails between scientific and marketing employees, and company drafts of documents in various stages before final drafts were published. These were not normal marketing documents because, as Warner-Lambert admitted, its marketing of Neurontin was criminal in that it promoted Neurontin for medical uses for which it had not received FDA approval.[14]

Accordingly, the documents had to be read together as individual components of a large plan to corrupt markets in which Neurontin had no right to participate, including the market for psychiatric uses, for neuropathic pain uses, and for bipolar uses. The documents also had to be analyzed in light of the use of euphemisms not readily apparent to lay persons or even to persons outside of Warner-Lambert and Pfizer. For example, the term "emerging uses" is a euphemism for the term "off-label." Many company documents analyzed markets and marketing campaigns for "emerging uses" among physician populations that would not ordinarily be exposed to Neurontin. In this way, Dr. King was able to read a combination of publication committee plans to arrange publications for Neurontin for off-label uses, operating plans that call for the use of such publications and the paid-for authors in continuing medical education settings, and the number of sales calls and attendees at such meetings and observe the number of exposures of

[13] *Id*. at ¶5.
[14] Fromson Decl., Ex. E at pp 13-14.

doctors to off-label marketing. Dr. King was also able to employ those observations and apply to them the known academic studies of how pharmaceutical markets exploit doctors to exchange information about drugs even in the absence of a scientific basis for safety or efficacy.[15]

Experts may interpret and explain technical documents as a basis of their opinions. In *In re Seroquel Products Liability Litigation*, the District Court allowed the experts to rely and discuss the internal corporate documents stating "[t]o rule otherwise would unduly restrict Plaintiffs' experts from explaining the bases of their opinions." 2009 WL 3806436 * 4 (M.D. Fla. 2009). The District Court also addressed the selection of documents for the experts and found "AstraZeneca's criticisms regarding the universe of documents the experts considered go to the weight to be accorded these experts' opinions, rather than their admissibility." *Id.; see also Securities & Exch. Comm'n,* 525 F. Supp. 2d at 70 (Court found that marketing expert was permitted to testify regarding the "meaning of contract terms. . . employed in the contract and industry practice in regard to such contracts" and that his expert testimony is "useful with respect to general industry observances in negotiating, drafting, reviewing and interpreting contracts"). Dr. King was given all of the documents, but even if he had not been provided by all of the documents, *Seroquel* stands for the proposition that fact would go to the weight of his testimony and not render the expert's testimony inadmissible.

Finally, Defendants' claim that Dr. King did not consider alternative explanations is incorrect. He wrote in his Report that he did indeed evaluate the possible explanations for doctors to prescribe Neurontin for things other than epilepsy and concluded that they did not explain the phenomenon. *See* Fromson Decl., Ex. A, ¶¶ 80-87. Neurontin had the least scientific support for the highest proportion of off-label prescriptions of any of 160 drugs. This became such a commonplace after the off-label campaign succeed that:

[15] Fromson Decl., Ex. A, King Report, ¶¶ 30-58, 67-97.

> The widespread use of Neurontin would further encourage doctors who may not have had direct contact with the drug company to prescribe the drug, because "widespread use of a drug may convey information about its safety and efficacy, and, for physicians, may imply 'accepted practice' and hence greater immunity to malpractice lawsuits. … **This]could lead to the dominance of one drug – not necessarily the most efficacious or safest – <u>despite the availability of close substitutes."</u>** [1] Berndt, Pindyck, and Azoulay, "Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs", *The Journal of Industrial Economics*, June 2003, 243-270

B. **The Nexus of Dr. King's Testimony to the Smith Case**

Similar to the national marketing documents, Dr. King's testimony is relevant to, and will be utilized by Plaintiff to demonstrate that Defendants breached their duty of care and that Defendants had notice of the deleterious effects posed, depression/suicidality, by ingestion of their drug Neurontin. As detailed in Plaintiff's opposition to Defendants motion *in limine* to exclude the marketing documents, the manufacturer's <u>knowledge</u> of off-label use with its drug is inextricably intertwined with a manufacturer's duty to disclose material facts about risks with the drug. Defendants were on notice both of the risks of depression and of the substantial off-label use of Neurontin. Dr. King's testimony is probative of Defendants' negligence.

Dr. King's testimony will demonstrate the extent of Defendants knowledge and state of mind in regard to their off-label promotion of Neurontin for unapproved uses. The illegal promotion scheme found by Dr. King, admitted by Warner-Lambert, and continued by Pfizer is the same off-label promotion that Defendants used on Mr. Smith's prescribing medical providers via direct sales representative detailing to the doctors' offices, (MDL Docket No. 1679, Ex. 13), none of whom disclosed a single word of negative information about Neurontin. The result of the illegal promotion is that Mr. Smith was prescribed Neurontin for pain — an off-label, unapproved use. MDL Docket No. 1679, Ex. 12 at 28:14-28:19. Although Defendants acknowledge it was inappropriate to detail physicians other than neurologists and epileptologists

(MDL Docket No. 1679, Ex. 14 at 45:8-45:25; *see* MDL Docket No. 1679, Ex. 15 at 009942), Defendants detailed Mr. Smith's neurosurgeon, an orthopedist, and a nurse. In doing so, Defendants, who breached their own internal standards, fraudulently represented to Mr. Smith's prescribing physicians that Neurontin was safe and/or efficacious for indications never approved for use by the FDA (i.e., pain and neuropathic pain).

Defendants' sales representative actively promoted Neurontin to Mr. Smith's orthopedist, Dr. Mackey, and the doctors in his medical practice on approximately 69 occasions with respect to Neurontin. MDL Docket No. 1679, Ex. 16. Dr. Mackey testified that Defendants detailed him about "neuropathic pain", which is an off-label, unapproved use by the FDA. MDL Docket No. 1679, Ex. 12 at 76:23-77:16.

Defendants' sales representative also actively promoted Neurontin to Mr. Smith's healthcare provider, Nurse Pamela Krancer, on approximately 27 occasions with respect to Neurontin. Defendants' sales representative Ashley Pippin planned to "probe" into where Nurse Krancer was dispensing Neurontin and "get help through her with other surgeons." MDL Docket No. 1679, Ex. 17. Defendants' sales representatives clearly acted on this "probe" plan as evidenced by the more than 300 occasions in which Defendants detailed the medical practice and distributed Neurontin samples[16] to the medical practice where both Mr. Smith sought treatment and Nurse Krancer worked. MDL Docket No. 1679, Ex. 18.

Defendants' sales representative also detailed Dr. McCombs, a neurosurgeon, on approximately three occasions with respect to Neurontin. MDL Docket No. 1679, Ex. 19.

None of Defendants' sales representatives informed Mr. Smith's prescribing medical

[16] Noteworthy, each distribution of a Neurontin sample to the medical practice also included the Neurontin Label which Defendants admit provided inadequate directions for unapproved uses. This admission is reflected in their 2004 guilty plea for distributing a misbranded drug. *See* MDL Docket No. 1200-3, Ex. 2.

providers of Neurontin's association with depression/suicidality. Furthermore, it is clear that whenever a sales representative provided samples or other materials, Neurontin's risk of suicidal and self injurious behavior, was not included in the labeling accompanying these materials. It is undisputed that Defendants pled guilty to (1) illegally marketing Neurontin for off-label purposes, and (2) misbranding the drug in that the label lacked adequate directions for use in those off-label populations[17].

Dr. King also concluded that the suppression of negative information concerning Neurontin was one of the reasons for the huge growth of off-label sales and prescriptions of Neurontin. In Mr. Smith's instance, Defendants failed to disclose to any of the prescribing doctors what they knew concerning the risks of Neurontin. Dr. King's testimony concerning this suppression was found by Judge Saris in the MDL to be directly relevant to the "state of mind" and "intent" of Defendants.[18]

Dr. King's testimony is evidence of Defendants' reckless and wanton conduct. Dr. King will testify that the irrespective of the reasons behind the off-label uses of Neurontin, Defendants were aware of the more than 90% off label usage.[19] Dr. King also opines on the suppression of negative information. These two concepts intersect in March of 2001, where Defendants acknowledged that they are unsure of the safety of Neurontin in populations other than Epilepsy[20]. Since the company was seeking an approval in the neuropathic pain population, it was felt that it was necessary to review the safety in this population, but none of the other off-label populations[21]. Defendants knew that their product was being substantially used in populations where Defendant was unsure of the safety is strong evidence of reckless conduct.

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[17] Fromson Decl., Ex. E, pp 13-14.
[18] Fromson Decl., Ex. F, at 13-14 Excerpts from the July 2009 pre-trial hearing for *Bulger v. Pfizer Inc.*
[19] Fromson Decl., Ex. A, King Report, p. 17, n.39.
[20] Fromson Decl., Ex. G, pp 2-4.
[21] *Id*.

Moreover, Plaintiff's decedent's prescribing physician, Dr. Mackey, testified that he was not aware of various important information concerning problems with Neurontin, depression and suicide, and that had he been told of these problems with Neurontin, he "[c]ertainly" would have given Mr. Smith specific warnings and told him to be observant about side effects; and Nurse Krancer testified that had Defendants told her that Neurontin was associated with increases in depression and suicide, she would have educated the patients on these potential side effects. *See* MDL Docket No. 1678, Further Statement, ¶¶ 15-23, re Learned Intermediary. Mr. Smith's prescribing medical providers, Dr. Paul McCombs and Dr. Mackey, testified about the material information suppressed by Defendants. Both doctors, in discussing their prescribing practices and risk/benefit analyses for prescribing a drug to Mr. Smith, wanted to know about suicide attempts during clinical trials; depression adverse events during clinical trials, and whether depression and suicidality were side effects. MDL Docket No. 1679, Ex. 11 at 12:3-12:19, 12:20-14:23, 28:10-29:19; MDL Docket No. 1679, Ex. 12 at 34:14-36:25. Therefore, this testimony by Dr. King is directly applicable to Richard Smith and Plaintiff's claims in this case.

C. Dr. King Did Form and Express Opinions About the Extent to Which Defendant's Illegal Marketing Campaign Led to Improper Off-label Prescriptions.

As Dr. King stated in his report, only 5 and 10 per cent of Neurontin's total prescriptions were for on-label uses, that is, epilepsy or, after FDA-approval in 2002, post-herpetic neuralgia.[22] In other words, over 90 per cent of the prescriptions for Neurontin were off label.[23] As he also found, Neurontin had the highest percentage of off-label use of any of 160 commonly-prescribed drugs and the highest percentage of prescriptions without scientific support.

Finally, as Dr. King also stated in his Report, the highest number to which one could

[22] Fromson Decl., Ex. A, King Report; *see, e.g.*, p. 17, ¶ 18, and narrative summary in footnote 39.
[23] Fromson Decl., Ex. A, King Report; see also Figure 8 in Report.

anticipate off-label sales of Neurontin without improper promotion is twenty-one percent[24]. In sum, the total legitimately-anticipated prescriptions of Neurontin include not more than 10 per cent on label plus the maximum of 20 per cent of all sales as legitimate off-label, i.e. prescriptions written without illegal promotion as a cause of the prescription choice.

That means that Dr. King reported that seventy per cent, at least, of Neurontin prescriptions were the result of the illegal marketing campaign and promotion. It is enough that he described it for defense counsel; he is not obligated to understand it for them.

But, to make it clear, Dr. King also explained it in testimony:

> I have sort of a before and after study, before there's illegal promotion and after there's illegal promotion, that gives me a sense of what's the magnitude, how big is the effect of the off-label marketing. And it's quite substantial. It goes from 15 percent in 1994 when Neurontin is first introduced, roughly 15 percent of the uses are for off-label, unapproved uses of the drug. So let's just assume that all of those are fine and all of those are perfectly legal. By 2002 what do you see? You see that 94 percent of Neurontin's uses are for off-label and unapproved uses. So, as a crude measure of what's the effect of the off-label marketing, it would be the difference between the 15 percent and the 94 percent.[25]

Dr. King is not a damage witness and, thus, this is not a case where damages are based upon some quantification of the extent of off-label marketing. As such, it was not essential to Dr. King's opinions to calculate what percentage of sales were due to off label uses. His opinion is adequate for his purposes and more than adequate to counter for Defendants' criticism.

Moreover, contrary to Defendants' assertions that Dr. King did not take into consideration other factors which might have contributed to the increase in Neurontin sales (MDL. Docket No. 1919 at 5), Dr. King testified as follows:

> THE COURT: Well, now, now to my question. How can you tell how much of that percentage is as a result of illegal marketing rather than legal doctor prescription, if you can.

[24] Fromson Decl., Ex. A, King Report; *see, e.g.,* p. 17, , ¶ 18, and narrative summaries in footnotes 40-44.
[25] Fromson Decl., Ex. H, Transcript, *Shearer v Pfizer Inc.*, April 1, 2010, at pp. 50:23-51-10.

THE WITNESS: I think the easiest way to do that is to look at -- we have, we have information on the sales over time of the drug for various indications. And what the judge says is correct, that a doctor is entitled to prescribe an approved drug for an unapproved use in the exercise of his best clinical judgment. And what we, what I did was, I looked at what do sales look like of a drug for a particular indication, say bipolar, for instance, which is an off-label use, before the company started marketing for, started marketing for the unapproved uses of the drug. And what you find is that the sales at that point are quite low. They're consistent with what we know from other evidence. There's an academic study out there that says on average for a drug you would expect typically 15 to 20 percent of the uses of the drug might be for unapproved or off-label uses. And when you look at the Neurontin sales prior to when the defendants started promoting for off-label uses, you find that roughly 15 percent of the sales in some of these off-label uses occurs. So, that to my mind gave me an indication of what you would expect in the ordinary course of events; what you would expect for doctors who, let's just say hypothetically there was no illegal promotion up to a certain point, what would you expect to see in terms of off-label usage. And we do see low levels of off-label prescriptions. So let's just assume that all of those are legitimate and that there's nothing wrong with it. Then what happens is a company starts marketing off-label. And then if you look at the sales graphs, what happened is there's a very dramatic increase in the off-label uses, which I attribute to the effects of the off-label marketing. So that's -- I have sort of a before and after study, before there's illegal promotion and after there's illegal promotion, that gives me a sense of what's the magnitude, how big is the effect of the off-label marketing. And it's quite substantial. It goes from 15 percent in 1994 when Neurontin is first introduced, roughly 15 percent of the uses are for off-label, unapproved uses of the drug. So let's just assume that all of those are fine and all of those are perfectly legal. By 2002 what do you see? You see that 94 percent of Neurontin's uses are for off-label and unapproved uses. So, as a crude measure of what's the effect of the off-label marketing, it would be the difference between the 15 percent and the 94 percent.

Q Dr. King, did you prepare a graph that shows Neurontin sales by indication, a bar graph, on-label and off-label during the years between 1995 and 2002?

A Yes, I did.[26]

Moreover, that there may be factors that was not considered by Dr. King, that information would go to the weight of the evidence not the admissibility of his testimony.[27]

[26] Fromson Decl., Ex. G Excerpts from Shearer Transcript at 49:13-51:14, *see also* Ex. B at ¶ 9.

[27] *See Smith v. Pfizer Inc*., where the plaintiff brought suit claiming that Pfizer's drug, Zoloft, resulted in suicide. 2001 U.S. Dist. LEXIS 12983 at *1, 2 (D. Kan. 2001). The District Court allowed the testimony of plaintiff's specific causation expert, finding that "[d]efendants' claim that [the expert] has failed to account for other potential causal factors goes to the weight and credibility of the opinion, not its admissibility." *Id.* at *28.

D. Dr. King Was Not Improperly Influenced By Plaintiff's Counsel

As Dr. King recites in his Declaration and as he testified at his deposition, he was provided with a hard drive that contained millions of pages of documents. In fact, this hard drive contained the entire document production produced by Defendants.[28] Furthermore, he used Keith Altman as a tool to make graphs. Defendants' attack on Dr. King (and Mr. Altman) is groundless. Judge Saris has already dismissed this as the equivalent of using a secretary.[29]

Dr. King directed Mr. Altman to provide him with certain data. The data were compiled under Dr. King's direction and supervision by Mr. Altman.[30] Dr. King notes that to his knowledge, Defendants have not challenged the accuracy of the data that was compiled by Mr. Altman and indeed company records corroborate the data.[31] There is nothing improper about an expert using Mr. Altman in this way.

In *In re Viagra Products Liability Litigation,* 658 F. Supp. 2d 950, 963 (D. Minn. 2009), an expert, after reviewing voluminous materials in order to reach her expert conclusions, utilized a chart and a summary prepared by Mr. Altman which summarized the number of adverse events reported for Viagra. The District Court found that there was no evidence that the chart prepared for the expert was not reviewed or verified by the expert, and that the expert had a long-time working relationship with the individual who prepared the chart and summaries of data. The Court denied the motion to exclude. *Id.* at 964. The Court noted that Defendants were entitled to cross-examine the witness about any alleged "weaknesses" in methodology. *Id.* at 963.

Defendants' claims that Plaintiffs' counsel selected the documents for Dr. King to review

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[28] Fromson Decl. at ¶ 3.
[29] Fromson Decl., Ex. I.
[30] Fromson Decl., Ex. B at ¶ 7
[31] *Id.*
[35] Fromson Decl., Ex. J, King Dep. at 81:7-82:2.

and influenced his work is an intentional deception. All information that was provided by Plaintiffs' counsel came from defense counsel; Dr. King had all of the materials produced by Defendants available to him:

> Q. What other documents besides those listed on attachment B did you review in connection with your work in this case?
>
> A. Well, the attorneys provided me with a hard drive with a daunting number of documents, so there's all sorts of internal company memoranda or e-mail communications or marketing plans or business plans or publication plans, sales analyses, you know, transcripts of conversation, contacts with outside medical education companies. There is a large body of evidence, and I reviewed an awful lot of documents. And out of those, I selected these as examples or as representatives for the points I was trying to make.
>
> Q. And how did you make that selection?
>
> A. I tried to find things that I thought were the -- made the point most clearly, most succinctly, and were representative of what I had discovered in reading various documents.[35]

The hard drive that Dr. King refers to is the hard drive of the complete document production as produced by Defendants.[36] Dr. King was also provided with a mechanism to search these documents. It is a sham for Defendants to claim that Plaintiffs did something improper in providing the complete document collection to Dr. King.

Dr. King, independent of Mr. Altman and anyone employed by counsel, searched the hard drive himself for materials that he thought were relevant to the development of his opinions. These searches are precisely what an expert is expected to do. In addition, Defendants were provided with a computer disk with all of the materials used to respond to Dr. King's inquiries. Plaintiffs' counsel spent more than two hours on the phone in advance of Dr. King's deposition answering Defendants' questions as to the sources of each set of data provided to Dr. King. Defendants were provided with a full and fair opportunity to cross-examine Dr. King on the

[36] Fromson Decl. at ¶ 3.

accuracy of any of the data in his report. Finally, Defendants do not attack the data itself, which disposes of this issue:

> Here, there is no indication that the chart Plaintiffs' counsel prepared for Dr. Blume was incapable of verification or meaningful review. Pfizer does not argue that the chart misrepresents the data available

In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d at 964.

Lastly Defendant allude to "an outside firm" that collected and classified data provided to Dr. King. There is nothing wrong with, and indeed it is normal for, an expert to rely on others for data or analysis. Defendants fail to disclose that the "outside firm" is Dr. Cheryl Blume, an expert in this case whose opinions have already been found to be reliable and admissible by Judge Saris in the MDL. Dr. King requested that the various indications specified in the data provided by Defendants be placed into certain buckets by indication. Dr. Blume, reviewed the different indications and did exactly what Dr. King requested. In addition, Dr. King states that he also relied on Dr. Blume, another expert, for certain Verispan data on numbers of prescriptions. Dr. King explained that "[i]t is normal and reasonable for economists and marketing experts to rely on persons with technical knowledge for specific data compilations."[37]

E. Judge Saris, MDL Presiding Judge, and Judge Young Have Already Denied Defendants' Motion to Exclude Evidence of Defendants' Marketing and Illegal Promotion of Neurontin And to Exclude Dr. King

Defendants are re-arguing a matter that has been denied. Judge Saris has already ruled that marketing information is admissible to demonstrate recklessness and suppression. On June 5, 2009, Judge Saris issued an Electronic Order relating to a similar motion interposed by Defendants — Defendants' motion to, *inter alia*, exclude national marketing documents from evidence — and stated the following: "[t]he request to remove evidence related to national marketing is denied." On June 22, 2009, Defendants again attempted to exclude evidence of

[37] Fromson Decl., Ex. B at ¶ 8.

marketing or advertising in the MDL, basically on essentially the same ground, in *Bulger v. Pfizer Inc.,* which Judge Saris denied by an Electronic Order on July 24, 2009.

In the recent case of *Shearer vs. Pfizer Inc.*, which was tried by Judge Young in the District of Massachusetts at the behest of Judge Saris, Defendants raised essentially the same motion after the testimony of Dr. King and Defendants motion was overruled.

> THE COURT: Do you want to argue this afternoon.
>
> MR. OHLEMEYER: No, I just want to make, I want to make a contemporaneous objection. I can make it in the morning to make a record. I just don't want there to be an issue of me not making it contemporaneously.
>
> THE COURT: And what is it?
>
> MR. OHLEMEYER: I would like, based on, based on the cross-examination of Professor King, I would like to move to strike under Rule 702 because his testimony doesn't assist the trier of fact in understanding the facts at issue.
>
> THE COURT: Noted. Overruled. Thank you. We'll recess.[38]

For those reasons alone, the Court should deny the portion of Defendants' motion regarding relevancy. Furthermore, the admissibility of marketing information is the subject of a separate motion *in limine*. Plaintiffs incorporate their opposition to Defendants' motion by reference, but Plaintiff will use the marketing evidence generally to (1) show the recklessness of the company and (2) show the effect of the suppression of negative information.

Defendants' motion is also untimely. The MDL court ordered the parties to file Daubert motions for generic experts by December 15, 2007. MDL Docket No. 582. While Defendants challenged several Plaintiffs' experts, Defendants never raised a challenge to Dr. King at that time. Now in the guise of a motion *in limine*, they raise just such a challenge. This is counter to the MDL process, and Plaintiff respectfully requests that this Court deny the motion as it is untimely and more properly made before the MDL Court.

[38] Fromson Decl., Ex. H, *Shearer v. Pfizer Inc.*, Trial Transcript at p. 165:3-15.

Dated: April 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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